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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,339	03/29/2001	Sara Fuchs	FUCHS=2A	3100

1444 7590 10/14/2003

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WASHINGTON, DC 20001-5303

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/14/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/820,339

Applicant(s)
Fuchs et al

Examiner
Robert C. Hayes, Ph.D.

Art. Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 30, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-19 and 23-31 is/are pending in the application.
- 4a) Of the above, claim(s) 10, 11, 13, 23, 24, and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 9, 12, 14-19, 25, and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 8-19 and 23-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 13 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

1. The amendment filed 6/30/03 has been entered.
2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Israel on 5/07/97. It is noted, however, that applicant did not file a certified copy of the Israel priority application in parent application 09/423,398 as required by 35 U.S.C. 119(b).
3. Newly submitted claims 23, 24, 26 & 29(in part) are directed to an invention that is independent or distinct from the invention originally claimed for the reasons made of record in Paper No: 11 (mailed 1/30/03).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23, 24, 26 & 29(in part) are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claims 8i-ii & iv, 9i-ii & iv, 10-11, 13, 23, 24, 26 & 29(in part) that are drawn to inventions nonelected with traverse in Paper No. 10. A *complete reply* to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144), such as rewriting the claims to only the elected invention. See MPEP § 821.01.

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It is noted that Applicants' arguments have already been addressed in Paper No: 11 (mailed 1/30/03), as it relates to the *restriction* requirement from Paper No: 9 (mailed 9/30/02).

4. The rejection of claims 8-9 & 17 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn due to the amendment of the claims.

5. The rejection of claims 8-9, 12 & 14-19 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to the amendment of the claims to recite appropriate functional language.

6. The rejection of claims 8-9, 12 & 14-19 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Applicants' arguments filed 6/30/03 have been considered but are not found persuasive.

9. New claims 8-9, 12, 14-19 & 28-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application is apparent for the broader recitation of "comprising residues 61-76 of SEQ ID NO:2 and/or residues 184-210 of SEQ ID NO:2" in base claim 8; thereby, constituting new matter. In contrast to Applicants' assertions on page 10 of the response, no such basis exists in the paragraph bridging pages 24 & 25 of the specification (i.e., *pp# 0080*).

10. Claims 8-9, 12, 14-19 & 28-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 11 (mailed 1/30/03), and as follows.

Applicants argue on page 10 of the response that "Example 14 (Product by Function) of the Revised Interim Written Description Guidelines... is also directed to variants of a specific sequence for which activity is essential to the operation of the claimed invention". The Examiner agrees. However, the claims remain not limited to only a "human" DNA molecule as alternatively discussed in Example 17 of the Written Description Guidelines, in which no nonhuman species of acetylcholine receptor DNAs are described within the specification (i.e., as

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it relates to a polypeptide with “at least 95% sequence identity”). Nor are the claims limited to encoded fusion polypeptides that increase “solubility” or create a “protease target sequence” for “further processing” (e.g, see pg. 30 of the specification), in which especially no DNA sequences encoding any putative fusion sequence are described (i.e., as it relates to claims 8(viii), 9(viii) & 30-31). Nor are any different open reading frames that merely “comprise” fragments of SEQ ID NO:1 described (i.e., as it relates to claim 9((iii)(v)(vii), 12 & 14), as previously made of record.

Analogous to the situation decided in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), “an adequate written description of a DNA [product] requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself”. *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) held that claims directed to mammalian FGF’s were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only a single encoded human polypeptides species (i.e., SEQ ID NO:2) has been described in the instant specification.

Accordingly, as it relates to the required components necessary to practice the claimed method, the court held in *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) that:

“One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have

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previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is".

and that:

"A description of a genus of cDNAs [products] may be achieved by means of a recitation of a representative number of cDNAs [products], *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus* [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218".

Thus, Applicants are not reasonably in possession of the claimed genus encompassing nonhuman acetylcholine receptor DNAs, etc. at the time of filing the instant application, as currently claimed; thereby, not meeting the written description requirements under 35 U.S.C. 112, first paragraph.

Applicant is again directed toward the Revised Interim Utility and Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999.

11. Claims 8-9, 12, 14, 16-19 & 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Schoepfer et al. (1988), for the reasons made of record in Paper No: 11 (mailed 1/30/03), and as follows.

Applicants argue on page 13 of the response that "[a]s amended, claim 8 recites ... closed language". In contrast to Applicants' assertions, claim 9 still recites "a DNA molecule **comprising...**", which is open, and not closed language, and in which Schoepfer also teach

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sequences fused to (viii) (i.e., as it relates to claims 8 & 30). Thus, Applicants' arguments are moot.

12. Claims 8-9, 12, 14, 16-19 & 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Talib et al. (1991; IDS Ref #AM), for the reasons made of record in Paper No: 11 (mailed 1/30/03), and as follows.

Applicants again argue on page 13 of the response that "[a]s amended, claim 8 recites ... closed language". In contrast to Applicants' assertions, claim 9 still recites "a DNA molecule comprising...", which is open, and not closed language, and in which Talib also teach sequences fused to (viii) (i.e., as it relates to claims 8 & 30), as well as encoded fragments of SEQ ID NOs:1 or 2 (i.e., as it relates to claims 8 (vi)(vii)(viii), 9(vi)(vii)(viii). Thus, Applicants' arguments are moot.

13. Claims 8-9, 12, 14, 16-19, 25 & 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Barchan et al. (1995; IDS Ref #AO).

Barchan et al. teach isolation of a human AchR DNA that encodes a polypeptide inherently capable of suppressing the autoimmune response of an individual to the acetylcholine receptor, which comprises, and consists of, the nucleotides 1 to 363 and nucleotides 364 to 630 of SEQ ID NO:1, as well as the fusion of any or all fragments of SEQ ID NO:1 (i.e., pgs. 9172-9174, Fig. 2; as it relates to claims 8-9, 12, 14, 25 & 27-30). Barchan's DNA is cloned in

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prokaryotic expression vector, pET8C, and transfected in *E. coli* host cells in a method to express the protein, which includes fused protein sequences to these fragments (i.e., pg. 9173; as it relates to claims 16-19).

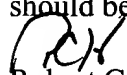
14. Applicant's amendment and submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 6/30/03 prompted the new ground(s) of rejection presented in this Office action: Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(I) and MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

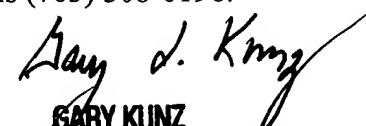
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Robert C. Hayes, Ph.D.
October 6, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
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